

March 17, 1999

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To: Dockets Management Branch, HFA-305

From: Vivian Gilliam, HFS-215

The information enclosed should be placed in the Docket No. 95F-0150, FAP 5B4461

Any additional information needed may be addressed to Vivian Gilliam at (202) 418-3167.

Sincerely,

Vivian Gilliam  
Direct Additives Branch, HFS-215  
Division of Petition Control  
Center for Food Safety  
and Applied Nutrition

Attn: Jennie Butler

95F-0150

EAI

Clariant GmbH  
FAP No. 5B4461

**ENVIRONMENTAL ASSESSMENT -- AMENDED**

**1. Date of Revised Environmental Assessment:**

December 21, 1998

**2. Name of Petitioner:**

Clariant GmbH

**3. Address:**

The Petitioner's business address is Clariant GmbH, BU Additive, Ludwig-Hermann Str. 100, D-86368, Gersthofen, Germany. All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110.

**4. Description of the Proposed Action**

The action requested in this Petition is the amendment of an existing Food Additive Regulation. Its purpose is to permit the safe use of a new substance as an antioxidant and/or stabilizer in the production of polyolefin food-contact articles. If the requested action is taken, the substance will be intended to compete with, and replace, other stabilizers currently in use.

The substance which is the subject of this petition is 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, 2,2,4,4-tetramethyl-, hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized [CAS Reg. No. 202483-55-4]. The additive is referred to hereinafter by the trade name Hostavin N 30. This petition requests amendment of 21 C.F.R. § 178.2010 to provide for the safe use of Hostavin N 30 at levels not to exceed 0.5 percent by weight of olefin

polymers complying with § 177.1520(c) items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene, and in olefin polymers complying with items 2.1, 2.2, 3.1 and 3.2, having a specific gravity of not less than 0.94, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from ethylene, in containers of at least 18.9 liters (5 gal) in volume. The stabilizer is also proposed for use at levels not to exceed 0.3% in olefin polymers complying with items 2.1, 2.2, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 4.0 of Section 177.1520(c), having a specific gravity of less than 0.94, in containers of at least 18.9 liters (5 gal) in volume, and at levels of 0.2% of those polymers in molded articles and films with aqueous foods of Types I, II, IV-B, VI, and VIII with no restriction on the amount of food contacted.

The additive will be manufactured by Petitioner at its facilities located in Gersthofen, Bavaria, Germany.<sup>1/</sup> The Petitioner does not manufacture finished food-contact articles with the use of the subject additive; rather, the stabilizer, either alone or as a component of formulated polyolefin resins, will be sold to processors that are involved in the manufacture of food-contact articles. Thus, the additive is expected to be used at a number of different production sites throughout the United States. Food-contact materials containing the subject additive will be used in patterns corresponding to national population density, and will be widely distributed across the country. Consequently, based on current EPA projections, it is expected that disposal will occur

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<sup>1/</sup> This facility was acquired by Petitioner from Hoechst AG, the previous holder of this petition, and is the same facility discussed in the previous EA for this petition, dated November 10, 1995.

nationwide, with up to 76% of the materials ultimately being deposited in land disposal sites, and up to 24% being incinerated. (These figures reflect expected disposal patterns for articles that are not collected for recycling; the use of the stabilizer at the low level proposed clearly will have no impact on recycling rates for the finished food containers.)

Hostavin N 30 is intended to be used as an antioxidant and/or stabilizer to provide long-term light and thermal stability to the polymer. Consequently, it is expected that olefin polymers stabilized with Hostavin N 30 most typically will be employed in the production of large-volume and/or repeated-use food-contact articles such as crates, drums, and pails, which require long-term stability to environmental stress conditions. The use of Hostavin N 30 in this manner will be in place of other antioxidants and/or stabilizers that are currently cleared, and thus will not affect the potential uses or disposal of the polyolefins in which it is used or of the finished articles fabricated from these polymers. Thus, approval of the action proposed herein may not reasonably be expected to have any significant environmental impact from this standpoint.

The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other retail food contact material in current use. Therefore, there are no special considerations regarding the environment surrounding the disposal of food-contact articles containing Hostavin N 30 when used as proposed.

## 5. Identification of Chemical Substance that is the Subject of the Proposed Action

The additive that is the subject of this Petition is identified below.

**Chemical Name:** 7-oxa-3,20-diazadispiro[5.1.1.1.2]-heneicosan-21-one, 2,2,4,4,-tetramethyl-, hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized

**CAS Registry Number:** 202483-55-4

**Average Molecular Weight:** 1300 (minimum)

**Physical Description:** almost white solid

**Impurities:** Possible byproducts present in Hostavin N 30 are discussed in detail in Section A of this Petition. The information provided therein should be treated as confidential. These components are co-active ingredients rather than unwanted impurities.

## 6. Introduction of Substances into the Environment

FDA's regulations no longer routinely require information about environmental introductions resulting from the production of FDA-regulated substances. No extraordinary circumstances apply to the manufacture of Hostavin N 30. Consequently, information regarding the manufacture of the stabilizer by the Petitioner is not presented here.

The action requested by this Petition is the listing in the Food Additive Regulations of an additional product for use as an antioxidant and/or stabilizer in the production of food contact articles prepared from olefin polymers complying with 21 C.F.R. § 177.1520. The additive is intended for use (1) in quantities not to exceed 0.5 weight-percent in propylene homopolymers

and copolymers, (2) in quantities not to exceed 0.5 weight percent in high-density polyethylene, and (3) in an amount not exceeding 0.3% in low-density polyethylene and other olefin polymers where the finished food contact article will hold food in quantities of at least 18.9 liters except that films and molded articles containing not more than 0.2 percent by weight may contact aqueous foods (Types I, II, IV-B, VI, and VIII), with no restrictions on the amount of food contact. Thus, when used as intended, the additive will be present as a functional component of finished food packaging materials at concentrations well below 5% by weight.

The estimated market volume for the additive has previously been provided in Appendix X of the petition; this projected market has not changed. In the course of its use, approximately 1% or less is expected to be lost during incorporation of the stabilizer into food-contact materials and fabrication of the finished article. Thus, at least 99% of the production of the substance is expected to be present as components of finished food-contact articles. The quantities represented by these percentages are calculated in Appendix X. The Petitioner considers this information to be valuable trade secrets. Consequently, it should be protected from unauthorized disclosure in accordance with FDA's Public Information Regulations and 21 C.F.R. § 25.51(a).

Little or no introduction of Hostavin N 30 into the environment will result from its addition to food-contact polymers because the stabilizer is intended to be completely incorporated into food packaging materials. Moreover, the substance is expected to remain with the polymer throughout use of the food packaging material.

Disposal by the ultimate consumer of food-contact articles containing Hostavin N 30 will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. It is also possible that some portion of the articles in which the stabilizer is used will be collected for recycling; the rate at which recycling occurs will not be increased or decreased as a result of the use of the stabilizer in the polymer.

Hostavin N 30 contains only carbon, hydrogen, oxygen and nitrogen. No significant quantities of any toxic combustion products are expected as a result of the incineration of this product in a properly operated incinerator. More specifically, the possible combustion products of Hostavin N 30 include carbon dioxide ( $\text{CO}_2$ ), water ( $\text{H}_2\text{O}$ ), nitrogen ( $\text{N}_2$ ) and traces of  $\text{NO}_x$ .

The maximum quantity of nitrogen oxides that may be produced as a result of incineration of Hostavin N 30 may be calculated as follows. Of the potential oxides of nitrogen, the species containing the least amount of nitrogen on a weight basis is nitrogen dioxide (30% N). The worst-case assumption, then, is that all of the nitrogen released in the combustion of Hostavin N 30 will form nitrogen dioxide. Thus, for every kg of nitrogen released, as much as 3.3 kg of  $\text{NO}_2$  may be formed (i.e.,  $1 \div 0.3$ ). Hostavin N 30 contains approximately 6.7% of nitrogen by weight. Thus, each kg of Hostavin N 30 combusted will release at most 0.22 kg of  $\text{NO}_2$  ( $0.067 \times 3.3 \text{ kg}$ ).

As noted under Item 4 above, current EPA projections indicate approximately 24% incineration of non-recycled municipal solid waste. Thus, the maximum annual release of  $\text{NO}_2$  to the atmosphere from incineration of food-contact articles containing Hostavin N 30 as a result

of approval of this Petition may be estimated by multiplying the anticipated food-contact market volume for the stabilizer by: (1) 24%, to represent the fraction of materials expected to be incinerated; and (2) 0.22 to represent the maximum quantity of NO<sub>2</sub> that may be formed per unit weight of N 30. The result is orders of magnitude below the total annual NO<sub>2</sub> emission rate. Clearly, the possible release of nitrogen oxides from incineration of food-contact articles stabilized with Hostavin N 30 is of no concern at these levels.

When food packaging materials containing Hostavin N 30 are added to sanitary landfills, no significant amount of leaching of the substance from these materials into the environment is anticipated. This conclusion is based on the low levels of migration of the stabilizer from food-contact materials tested under exaggerative exposure conditions (from an environmental conditions standpoint) as shown in Section B of this Petition.

These studies involved extraction of a variety of different test specimens with food-simulating solvents under different conditions of exposure. Test specimens were prepared with various levels of N 30 in polypropylene copolymer, high-density polyethylene, and low-density polyethylene. Of most direct relevance to estimating potential leaching of Hostavin N 30 under environmental conditions are those studies involving exposure to 8% (v/v) aqueous ethanol. Depending upon the polymer type, Hostavin N 30 loading level, and extraction test conditions, the level of migration under exaggerative conditions relative to conditions of environmental exposure ranged from 0.07% to 3.5% of the amount of N 30 present in the test specimens.



Based on these results, the amount of Hostavin N 30 that may potentially become a component of landfill leachate per year may be estimated by multiplying the percentage of migration to 8% ethanol by (1) the total projected annual market volume for N 30 in food-contact applications, and (2) 76% to represent the maximum fraction of food-contact articles containing the additive expected to be disposed of via landfill. These calculations demonstrate that the concentration of Hostavin N 30 in landfill leachate will be extremely low. In addition, the ordinary introduction of these substances into the environment will not threaten a violation of the Environmental Protection Agency's regulations in 40 C.F.R. Parts 258 that pertain to landfills.<sup>2/</sup>

## **7. Fate of Emitted Substances in the Environment**

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of the food additive because as discussed above only small quantities, if any, of substances will be introduced into the environment as a result of use and disposal of the food additive. Therefore, the ordinary use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, for example, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

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<sup>2/</sup> EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

## **8. Environmental Effects of Released Substances**

No information need be provided on the environmental effects of substances released into the environment as the result of use and/or disposal of the food additive because as discussed above only small quantities, if any, of substances will be introduced into the environment as a result of use and disposal of the food additive. Therefore, the ordinary use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, for example, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

## **9. Use of Resources and Energy**

Documentation of the use of resources and energy is not required since (1) the proposed food additive is intended for the same use as other antioxidants and/or stabilizers for polyolefins, and (2) the proposed action will not materially change the potential uses of the food-contact articles in which the additive is used. Products with which Hostavin N 30 is expected to compete include various substances that are currently listed in 21 C.F.R. § 178.2010 for use as antioxidants and/or stabilizers for polyolefins.

## **10. Mitigation Measures**

No potential adverse environmental impacts have been identified for the proposed action. Therefore, there is no need to discuss mitigation measures.

## 11. Alternatives to the Proposed Action

No potential adverse environmental impacts have been identified for the proposed action. Therefore, there is no need to discuss alternatives to the proposed action.

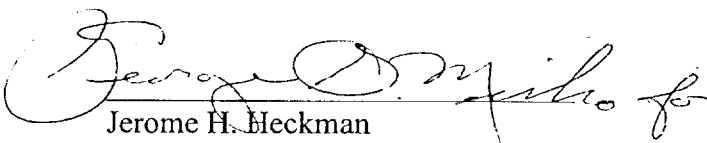
## 12. List of Preparers

- a. Dr. Bernhard Kammermeier, Clariant GmbH, Division of Pigments and Additives, BU Additives, Ludwig-Hermann-Str. 100, D-86368 Gerstofen, Germany.
- b. Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 600 West, Washington, D.C. 20001.

## 13. Certification

The undersigned certifies that the information presented herein is true, accurate, and complete to the best of his knowledge.

Date: 12/21/98

  
Jerome H. Heckman  
Counsel for Clariant GmbH



DEPARTMENT OF HEALTH & HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Public Health Service

## Memorandum

Date December 23, 1998

From Team Leader, Chemistry and Environmental Review Team  
Division of Product Policy (HFS-207)

Subject FAP 5B4461 - Hostavin N 30™ for Use as an Antioxidant and/or  
Stabilizer for Polyolefins Intended for Contact with Food

To Indirect Additives Branch (HFS-215)  
Attention: Dan Harrison, Ph.D.

Clariant, GmbH  
c/o Keller & Heckman  
Washington, DC 20001

Attached is the revised Finding of No Significant Impact (FONSI) for this petition. This FONSI supersedes the FONSI dated November 20, 1995. When the petition is ready to be regulated, please forward the revised FONSI and the petitioner's revised environmental assessment, dated December 21, 1998, to the Dockets Management Branch.

**Please do not send the confidential environmental information in Appendix 10 to the Dockets Management Branch.**

*Layla I. Batarseh*  
Layla I. Batarseh, Ph.D.

cc:  
HFS-200 Tarantino  
HFS-207 Batarseh  
HFS-246 RF/FAP 5B4461

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